

EXHIBIT D

Elizabeth Kavaler, M.D.

1 IN THE CIRCUIT COURT
2 TWENTY-SIXTH JUDICIAL CIRCUIT
3 CAMDEN COUNTY, MISSOURI
4 - - -
5 DONALD BUDKE :
6 Plaintiff, :
7 v. :
8 JOHNSON & JOHNSON, a NEW :
9 Jersey Corporation, ETHICON :
10 INC., a New Jersey Corporation, :
11 GYNECARE WORLDWIDE, a division :
12 of Ethicon, Inc., BECKY :
13 SIMPSON, M.D., P.C., d/b/a : Cause No.
14 LAKE AREA WOMEN'S CENTER : 10CM-CC00085
15 and BECKY SIMPSON, M.D., :
16 Defendants. :
17 - - -
18 OCTOBER 14, 2014
19 - - -
20 Videotaped deposition of
21 ELIZABETH KAVALER, M.D., taken pursuant
22 to notice, was held at the law offices of
23 Bryan Cave LLP, 1290 Avenue of the
24 Americas, New York, New York 10104,
commencing at 10:37 a.m., on the above
date, before Amanda Dee Maslynsky-Miller,
a Certified Realtime Reporter and Notary
Public in and for the State of New York.

25 - - -
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1 Since -- well, let me ask
2 you this: In connection with your
3 evaluation in this case, did you look at
4 any internal Ethicon documents?

5 A. No.

6 Q. That's something you've not
7 looked at in connection with any of your
8 reviews, correct?

9 A. That's correct.

10 Q. And am I correct that you
11 haven't reviewed any deposition testimony
12 of any Ethicon witnesses in connection
13 with this case?

14 A. That's correct.

15 Q. And am I correct that you're
16 not relying on any deposition testimony
17 from any witnesses from Ethicon in order
18 to offer your opinions?

19 A. That's correct.

20 Q. Have you reviewed any
21 depositions in connection with forming
22 your opinions in this case?

23 A. I've read depositions for
24 the case, yes.

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1 to -- you can hold it or whatever.

2 BY MR. SLATER:

3 Q. You have not seen the
4 deposition of Vincent Lucente, correct?

5 A. I have not.

6 Q. You haven't seen the
7 deposition of Miles Murphy that was taken
8 this year, have you?

9 A. I have not.

10 Q. You've not seen the
11 depositions that were taken of Jeffrey
12 Drazen or Gregory Kurfman of the New
13 England Journal of Medicine, have you?

14 A. I have not.

15 Q. Did you know those
16 depositions were taken before I just
17 asked you those questions?

18 A. Well, I knew about Lucente,
19 because it was alluded to in Dr.
20 Webber's. But the others I did not know.

21 Q. You have no opinions
22 regarding whether or not Ethicon's own
23 internal procedures and criteria for
24 whether or not the PROLIFT® should be

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1 marketed were met or not; that's not a
2 subject you've looked at, correct?

3 A. That's correct.

4 Q. Do you rely in any way on
5 the TVT, TVT-O, and the mid urethral
6 slings manufactured by Ethicon in any way
7 for your opinions in this case?

8 A. No. My opinions are all
9 based on PROLIFT®.

10 Q. Do you rely in any way on
11 the literature in connection with the TVT
12 and the TVT-O group of mid urethral
13 slings, in any way, in forming your
14 opinions in this case?

15 A. There's a little bit of
16 overlap in the material, so there's some
17 literature that will overlap in that
18 area.

19 But in terms of the actual
20 specifics of this case and the PROLIFT®
21 in this case, it's PROLIFT® literature.

22 Q. And what I'm getting at is,
23 I need to know if I should expect you, on
24 the witness stand, to be referring to any

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1 those -- that kind of -- that kind
2 of situation, that outcome.

3 BY MR. SLATER:

4 Q. You don't know the purpose
5 of the IFU from the perspective of
6 Ethicon, correct?

7 A. That's correct.

8 MR. BALL: Object to the
9 form.

10 THE WITNESS: I only know
11 from the perspective as a surgeon.

12 MR. SLATER: Move to strike
13 after "that's correct."

14 BY MR. SLATER:

15 Q. Let me just ask it again to
16 get it clean.

17 You don't know, as you sit
18 here now, the purpose of the IFU from the
19 perspective of Ethicon; is that a true
20 statement?

21 MR. BALL: Object to the
22 form.

23 THE WITNESS: That's
24 correct.

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1 BY MR. SLATER:

2 Q. You have no knowledge of
3 what the FDA regulations that apply to
4 the IFU require with regard to an IFU,
5 correct?

6 A. Correct.

7 Q. You have no idea what
8 testimony has been given by the people at
9 Ethicon who are responsible for the IFU
10 and the content of the IFU; you don't
11 know what they have said needed to be in
12 the IFU, correct?

13 MR. BALL: Object to the
14 form.

15 THE WITNESS: That's
16 correct.

17 BY MR. SLATER:

18 Q. Your opinions on the IFU are
19 limited to your perspective, based on
20 your medical practice for what you think
21 is necessary; is that fair?

22 A. That's fair, right.

23 Q. Have you ever studied what
24 other doctors think should be in an IFU

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1 product and how to compare it to
2 the way I was -- I was shown how
3 to use it.

4 But a lot of the information
5 in there is not something that I'm
6 looking to Ethicon to tell me.

7 BY MR. SLATER:

8 Q. I understand you're smart
9 and you don't need it, but other doctors
10 may not --

11 MR. BALL: I move to strike
12 the --

13 BY MR. SLATER:

14 Q. Let me ask you this --

15 MR. BALL: -- the
16 argumentative preamble.

17 BY MR. SLATER:

18 Q. -- do you think Ethicon has
19 an obligation, and had an obligation,
20 with the PROLIFT® IFU that when they put
21 information in it, that Ethicon thought
22 the information was truthful?

23 MR. BALL: Object to the
24 form.

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1 THE WITNESS: I don't put
2 this much thought into the IFU. I
3 don't know any surgeons who do put
4 that much into the IFU.

5 BY MR. SLATER:

6 Q. You don't have an opinion on
7 that?

8 A. I don't really have much of
9 an opinion on the IFU.

10 Q. Okay. If I understand
11 correctly, you, in your practice, didn't
12 even the read the section of the warnings
13 and indications and adverse reactions;
14 that wasn't even something that you
15 looked at, correct?

16 MR. BALL: Object to the
17 form.

18 THE WITNESS: I read it. I
19 looked at it. But that wasn't the
20 basis for which I would use it or
21 not use it.

22 BY MR. SLATER:

23 Q. Did I ask you if that was
24 the basis for which you would use it or

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1 obligation, from your perspective, when
2 they put information in the IFU, to give
3 truthful information?

4 A. I would assume that the
5 information they wrote down there was
6 truthful, to the best of their knowledge
7 at the time they wrote it.

8 Q. Did you think if Ethicon
9 made claims about the PROLIFT® or the
10 mesh in the PROLIFT®, clinical claims
11 about how it would actually work in the
12 body, that they should have data to
13 support making those claims?

14 MR. BALL: Object to the
15 form.

16 THE WITNESS: I didn't think
17 about that at the time and I still
18 don't --

19 BY MR. SLATER:

20 Q. I'm asking you now.

21 A. I don't -- I don't have a --
22 really have an opinion on that because I
23 don't have -- I don't really hold a lot
24 of stock in that.

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1 Q. Okay. When Ethicon listed
2 the risks and the complications in the
3 warning and adverse reaction sections,
4 did Ethicon have an obligation to list
5 those that they knew could occur with the
6 PROLIFT®?

7 MR. BALL: Object to the
8 form and the foundation.

9 MR. SLATER: You can answer.

10 THE WITNESS: The mesh that
11 they were using was the same mesh
12 I had already been using for three
13 or four years before the PROLIFT®.
14 It's the same mesh.

15 So I wasn't -- so I was more
16 interested in the application and
17 how the mesh was cut and how it
18 was implanted. So all the
19 warnings relating to the mesh
20 itself wasn't relevant anymore to
21 me, because I had been using it
22 for so many years.

23 MR. SLATER: Move to strike.

24 BY MR. SLATER:

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1 Q. You understand, Doctor,
2 you're not being put up on the witness
3 stand to talk about Dr. Kavaler's
4 experience as a doctor and just to, you
5 know -- your purpose is to be an expert
6 witness.

7 So I'm going to ask you --

8 MR. SLATER: I'm going to
9 move to strike that and try to ask
10 the question again, okay?

11 Do you want to object to the
12 form, too?

13 MS. STRAUSS: Yes.

14 MR. SLATER: You can do it
15 all you want.

16 MR. BALL: There wasn't any
17 question out there. So just go
18 ahead.

19 BY MR. SLATER:

20 Q. In the PROLIFT® IFU, when
21 Ethicon listed risks and complications
22 that could occur with the PROLIFT® in the
23 adverse reaction section, the warning
24 section, did Ethicon have an obligation

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1 to list those risks and complications
2 they knew would occur in some women?

3 MR. BALL: Object to the
4 form.

5 THE WITNESS: I don't know
6 what the obligation is. I'm not
7 an FDA person. I don't have any
8 association with that.

9 I can just tell you, as a
10 surgeon, what my expectations
11 would be.

12 BY MR. SLATER:

13 Q. I want to know, in response
14 to my question is that you don't have an
15 opinion on that?

16 A. On their obligations, I have
17 no opinion on their obligation.

18 Q. Okay. I want to talk about
19 the patient brochure for the PROLIFT®
20 now.

21 When Ethicon provided
22 information in the patient brochure for
23 the PROLIFT®, did Ethicon have an
24 obligation to provide truthful

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1 information or don't you have an opinion
2 on that?

3 MR. BALL: Object to the
4 form. Foundation.

5 THE WITNESS: So --

6 BY MR. SLATER:

7 Q. I'll ask it again.

8 A. Okay.

9 Q. When Ethicon published the
10 PROLIFT® patient brochure, did Ethicon
11 have an obligation to provide truthful
12 information in that document?

13 MR. BALL: Same objection.

14 THE WITNESS: I didn't use
15 their patient brochure, so I don't
16 really have an opinion on it.

17 BY MR. SLATER:

18 Q. That's fair. No opinion.

19 A. Yeah.

20 Q. Would the same answer hold
21 true -- rephrase.

22 Would it be accurate that
23 you have no opinion -- I'm sorry. I left
24 my phone on.

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1 Would I be correct that with
2 regard to the patient brochure, you would
3 have no opinion regarding whether or not
4 Ethicon needed to have a basis for any
5 claims made about the PROLIFT® --

6 MR. BALL: Object to the
7 form.

8 BY MR. SLATER:

9 Q. -- in that brochure?

10 MR. BALL: Object to the
11 form and foundation.

12 THE WITNESS: I didn't -- I
13 have to say, I didn't use the
14 patient brochure. It's not part
15 of what I gave to patients.

16 BY MR. SLATER:

17 Q. So it's not -- you have no
18 opinion on that?

19 A. I have no opinion.

20 MR. BALL: Object to the
21 form.

22 BY MR. SLATER:

23 Q. Just so I can maybe cut off
24 a lot of questions.

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1 the PROLIFT® about the potential risks
2 and complications, did Ethicon have an
3 obligation to disclose each of the risks
4 and complications that Ethicon knew would
5 occur to certain women with the PROLIFT®?

6 MR. BALL: Object to the
7 form and the foundation.

8 THE WITNESS: The patient
9 brochure is a tool for the doctor
10 to use to discuss with the
11 patient.

12 So the obligation is -- it's
13 universal for everybody to discuss
14 with the -- what the issues are.
15 I don't know what Ethicon's legal
16 obligations are. I don't know
17 anything about that.

18 The ethical obligations are
19 between the patient and the
20 doctor. And the patient brochure
21 is a tool.

22 MR. SLATER: Move to strike.

23 BY MR. SLATER:

24 Q. You're not familiar with any

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1 standard, criteria, any information that
2 would tell you what needed to be in a
3 patient brochure, correct?

4 A. I don't know legal
5 obligations.

6 Q. You don't know based on the
7 FDA regulations, correct?

8 A. That's right.

9 Q. You don't know what Ethicon
10 medical affairs thought needed to be in
11 the patient brochure, right?

12 A. That's right.

13 Q. You don't know what Ethicon
14 regulatory affairs thought needed to be
15 in the patient brochure, correct?

16 A. Right. Because my
17 obligation is to the patient. So what --

18 MR. SLATER: Move to strike
19 after "right."

20 MR. BALL: Please don't
21 interrupt her, Adam.

22 BY MR. SLATER:

23 Q. To the extent that any
24 claims were made in the patient brochure

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1 Q. So with regard to the
2 subject of collapse of the pores of the
3 PROLIFT® mesh in the body, that's not
4 something that you've looked at or
5 considered, correct?

6 A. Right, that specific
7 question.

8 Q. And you don't know if the
9 people within Ethicon were studying that
10 question, right? You haven't looked at
11 the internal documents or depositions, so
12 you don't know if Ethicon was looking at
13 that question, do you?

14 A. The clinical application of
15 the PROLIFT® is what's important. I
16 don't know what -- I don't know if
17 anybody was looking at that question on
18 any level.

19 MR. SLATER: Move to strike.

20 BY MR. SLATER:

21 Q. You don't know whether
22 Ethicon, people in Ethicon were looking
23 at that question, correct?

24 A. I don't know what people in

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1 Ethicon were doing for any -- I can't
2 speak to Ethicon.

3 Q. Have you ever studied
4 explanted mesh to determine the pore
5 sizes after explant?

6 A. I don't look at pore -- no,
7 I don't look at pore sizes.

8 Q. Have you ever had explanted
9 mesh from a patient that you were
10 involved in the treatment of where you
11 sent it to pathology and asked them to do
12 a study of the mesh pores and the pore
13 sizes?

14 A. I did not.

15 Q. So when you made the
16 statement earlier that, in your opinion,
17 the mesh pores for the PROLIFT® don't
18 collapse under 75 microns, that wasn't
19 based on you actually ever evaluating
20 mesh or looking at a study that evaluated
21 mesh to determine whether the pores
22 collapse down to that size, right?

23 MR. BALL: Object to the
24 form of the question.